

February 6, 2019



GT

Biopharma, Inc.

GT Biopharma Announces Closing of Private Placement Financing and Provides Business Update

Corporate, preclinical, clinical and regulatory advancements expected to position Company for a transformational 2019

Company on track to report topline Phase 2a data of GTB-1550 this quarter

First-in-class TriKE, GTB-3550, on track for H1 2019 commencement of first-in-human Phase 1 study for the treatment of AML, MDS and mastocytosis

LOS ANGELES, Feb. 06, 2019 (GLOBE NEWSWIRE) -- [GT Biopharma, Inc.](#) (OTCQB: GTBP and Euronext Paris GTBP.PA) ("GT Biopharma" or the "Company"), an immuno-oncology biotechnology company focused on innovative treatments based on the Company's proprietary NK-engager and Bispecific Antibody Drug Conjugate platforms, announced today that it has entered into a Securities Purchase Agreement with existing investors pursuant to which the Company has issued to the Purchasers Convertible Secured Notes in an aggregate principal amount of \$1,352,224, consisting of gross proceeds of \$1,052,224 and settlement of existing debt of \$300,000, which Notes shall be convertible into the Company's common stock, par value \$0.001 per share at a price of \$0.60 per share.

GT Biopharma also provided an update on its corporate progress, clinical status and anticipated milestones for its pipeline of immuno-oncology products based off the Company's proprietary bi-specific Antibody Drug Conjugate (ADC), Tri-specific Killer Engager (TriKE) and Tetra-specific Killer Engager (TetraKE) technology platforms.

"2018 represented a critical transitional phase for our Company, and I believe we have built significant momentum positioning us to achieve multiple corporate, clinical and regulatory milestone over the course of 2019. Importantly, we are very pleased to have closed the initial bridge financing, which represents an important step in our strategy to ensure we are properly funded to propel the Company to our next phase of growth. We are grateful to our loyal stockholders who have provided continued support of the Company through this investment," commented [Raymond Urbanski, M.D., Ph.D., Chief](#)

[Executive Officer](#) of GT Biopharma. “We continue focusing all of our resources on the flawless execution of our strategy and believe 2019 will be a transformational year for the Company, enabling us to drive significant shareholder value.”

Clinical Program Updates

GTB-1550 (OXS-1550): Most Advanced Bi-specific ADC Candidate

The Company’s most advanced bi-specific ADC in development, [GTB-1550](#), targets CD19+ and/or CD22+ hematological malignancies and is currently in the Phase 2 component of a Phase 1/2 Non-Hodgkin’s Lymphoma (NHL)/Acute Lymphocytic Leukemia (ALL) trial which is an open-label, investigator-led study.

GTB-1550 targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors. When GTB-1550 binds to cancer cells, the cancer cells internalize GTB-1550, and are killed due to the action of drug’s cytotoxic diphtheria toxin payload. GTB-1550 has demonstrated success in a Phase 1 human clinical trial in patients with relapsed/refractory B-cell lymphoma or leukemia.

Dr. Veronika Bachanova, Associate Professor of Medicine, Division of Hematology, Oncology and Transplantation at the University of Minnesota and the Principle Investigator for this study, is currently analyzing the final data and is anticipating submitting an abstract for the 2019 American Society of Clinical Oncology (ASCO) conference.

GTB-3550 (OXS-3550): TriKE product candidate

[GTB-3550](#) is the Company’s first Tri-specific Killer Engager (TriKE) product candidate being initially developed for the treatment of acute myelogenous leukemia (AML). GTB-3550 is a single-chain, tri-specific scFv recombinant fusion protein conjugate composed of the variable regions of the heavy and light chains of anti-CD16 and anti-CD33 antibodies and a modified form of IL-15. When the NK stimulating cytokine human IL-15 is used as a crosslinker between the two scFvs, it provides a self-sustaining signal that activates NK cells and enhances their ability to kill.

GT Biopharma recently announced that its Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) is now open and it is authorized to initiate a first-in-human Phase 1 study with GTB-3550, its first-in-class TriKE, for the treatment of AML, myelodysplastic syndrome (MDS) and mastocytosis. The study will be led by Principal Investigator, Erica Warlick, Associate Professor, Division of Hematology, Oncology and Transplantation at Masonic Cancer Center, University of Minnesota.

This single center, first-in-human Phase 1 clinical trial of GTB-3550 will enroll up to 60 subjects with CD33-expressing refractory/relapsed AML, high-risk MDS, or advanced systemic mastocytosis. Subjects will receive a single course of GTB-3550 given as 3 weekly treatment blocks. Each block consists of four consecutive 24-hour continuous infusions of GTB-3550 followed by a 72-hour break after Block #1 and #2. Disease response will be assessed by bone marrow biopsy performed between Day 21 and Day 42 after the start of the 1st infusion. Follow-up for response and survival continues through 6

months from treatment start. The primary objective from the Phase 1 dose finding portion of the study will be to identify the maximum tolerated dose (MTD) of GTB-3550 defined as the dose level that most closely corresponds to a dose limiting toxicity rate (DLT) of 20%. The primary objective from the Phase 2 extended portion of the study will be the potential efficacy of GTB-3550, measured using rates of complete and partial remission. Subjects experiencing clinical benefit and no unacceptable side effects may be considered for a 2nd course of GTB-3550 on a compassionate basis.

The Company believes that GTB-3550 could serve as a relatively safe, cost-effective, and easy-to-use therapy for refractory/relapsed AML, high-risk MDS and advanced systemic mastocytosis and could also be combined with chemotherapy and/or other agents as frontline therapy thus targeting a much larger patient population.

GT Biopharma's initial and ongoing work is being conducted in collaboration with the Masonic Cancer Center at the University of Minnesota under research agreements led by Dr. Jeffrey Miller, the Deputy Director and Dr. Daniel Vallera, Director, Section of Molecular Cancer Therapeutics.

GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize cancer therapies using proprietary TriKE technology developed by researchers at the university to target NK cells to cancer.

Upcoming Milestones Expected to Drive Value

- Announce topline results from Phase 1/2 trial of GTB-1550 in Q1 2019;
- Initiate Phase 1 first-in-human clinical trial of GTB-3550 for the treatment of Relapse/Refractory AML, High Risk MDS, and Advanced Systemic Mastocytosis in the first half of 2019;
- Conduct meeting for GTB-1550 with U.S. FDA in the first half of 2019;
- Advance ongoing GTB-C3550 IND-enabling studies & TetraKE pre-clinical program to target the larger solid tumor population and are working towards beginning clinical trials in 2019;
- Bolster executive management team and board with key expertise to continue to transform the Company;
- Participate in key scientific conferences;
- Make progress in advancing potential corporate and business development opportunities; and
- Uplist to a National Exchange.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE), Tetra-specific Killer Engager (TetraKE) and

bi-specific Antibody Drug Conjugate (ADC) technology platforms. Our TriKE and TetraKE platforms generate proprietary moieties designed to harness and enhance the cancer killing abilities of a patient's own natural killer, or NK, cells. Once bound to a NK cell, our moieties are designed to enhance the NK cell and precisely direct it to one or more specifically-targeted proteins (tumor antigens) expressed on a specific type of cancer, ultimately resulting in the cancer cell's death. TriKEs and TetraKEs are made up of recombinant fusion proteins, can be designed to target certain tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization. They are designed to be dosed in a common outpatient setting similar to modern antibody therapeutics and are expected to have reasonably low cost of goods. Our ADC platform can generate product candidates that are bi-specific, ligand-directed single-chain fusion proteins that, we believe, represent the next generation of ADCs.

For more information, please visit www.gtbiopharma.com.

Forward-Looking Statements

This press release contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding the potential acquisition, the likelihood of closing the potential transaction, our clinical focus, and our current and proposed trials. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as “believes,” “hopes,” “intends,” “estimates,” “expects,” “projects,” “plans,” “anticipates” and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Our forward-looking statements are not guarantees of performance and actual results could differ materially from those contained in or expressed by such statements. In evaluating all such statements, we urge you to specifically consider the various risk factors identified in our Form 10-K for the fiscal year ended December 31, 2017 in the section titled “Risk Factors” in Part I, Item 1A and in our subsequent filings with the Securities and Exchange Commission, any of which could cause actual results to differ materially from those indicated by our forward-looking statements.

Our forward-looking statements reflect our current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of our cash position and our ongoing ability to raise additional capital to fund our operations, (ii) our ability to complete our Phase 1 study of TriKe, GTB-3550 and or our Phase 2 trial of CTB-1550 and to meet the FDA's requirements with respect to safety and efficacy, (iii) our ability to identify patients to enroll in our clinical trials in a timely fashion, (iv) our ability to achieve approval of a marketable product, (v) design, implementation and conduct of clinical trials, (vi) the results of our clinical trials, including the possibility of unfavorable clinical trial results, (vii) the market for, and marketability of, any product that is approved, (viii) the existence or development of treatments that are viewed by medical professionals or patients as superior to our products, (ix) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, and social conditions, and (x) various other matters, many of

which are beyond our control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by our forward-looking statements.

We intend that all forward-looking statements made in this press release will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act, to the extent applicable. Except as required by law, we do not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this press release. Additionally, we do not undertake any responsibility to update you on the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

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